

## **EXHIBIT 2**



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
Rockville, MD 20857

April 4, 2005

**FILE COPY**

Mr. Peter O. Safir  
Covington and Burling  
1201 Pennsylvania Avenue, N.W.  
P.O. Box 7566  
Washington, D.C. 20004-2401

Dear Mr. Safir:

Your petition requesting the Food and Drug Administration to refuse to approve abbreviated new drug applications (ANDAs) referencing Arava (leflunomide) tablets, was received by this office on 03/31/2005. It was assigned docket number 2005P-0127/CP 1 and it was filed on 04/01/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Lyle D. Jaffe", is written over the typed name.

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management